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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,883	12/11/2001	Andrew Thomas Fagan	343355600034	2367

24325 7590 03/09/2006

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EXAMINER	
KOPPIKAR, VIVEK D	
ART UNIT	**PAPER NUMBER**
3626	

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,883	FAGAN ET AL.	
	Examiner	Art Unit	
	Vivek D. Koppikar	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *all received* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. Claims 1-36 have been examined in this application. This communication is the first action on the merits. As of the date of this communication, no Information Disclosure Statement (IDS) has been filed on behalf of this case.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "wherein at least a portion of the first metadata data structure is determined based upon an issue that arises in a subsequent biomedical development phase" in lines 14-15 of Claim 1 is indefinite. Specifically, it is not clear from a reading of the specification what the term "issue" encompasses. Appropriate clarification and/or correction is required.

For the purposes of examination, the examiner will interpret this phrase to mean that the metadata data structure is formatted or configured based upon the type of data that is obtained in the various phases of the biomedical development process.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 5,949,999 to Song in view of US Patent Number 6,917,944 to Prasad.

(A) As per claim 1, Song teaches a computer-implemented system that integrates data from a plurality of biomedical development phases (Song: Abstract and Col. 2, Ln. 10-23), comprising:

a database that stores data collected from the biomedical development phases (Song: Col. 5, Ln. 38-42);

at least one first graphical user interface connected to the database that collects data during the first biomedical development phase (Song: Col. 5, Ln. 27-31) (Song discloses that its software is adapted for product development processes regulated by the FDA which the examiner interprets to include biomedical or pharmaceutical processes); and

Song has the capability of producing and generating an audit trail of data (Song: Col. 2, Ln. 10-23).

Song does not teach the following limitations and features which are taught by Prasad:

the database further including a first metadata data structure that describes the data collected during a first biomedical development phase (Prasad: Col. 4, Ln. 29-35);

wherein the metadata data structure of the first graphical user interface is defined based at least in part upon the first metadata data structure so that the first graphical user interface collects data points as well as first metadata that is to be stored within the first metadata data structure, said first metadata describing the collected data points (Prasad: Col. 3, Ln. 49-60),

wherein at least a portion of the first metadata data structure is determined based upon an issue that arises in a subsequent biomedical development phase (Prasad: Col. 2, Ln. 1-18),

wherein at least a portion of the first metadata data structure contains links to another metadata structure associated with the subsequent development phase (Prasad: Col. 3, Ln. 8-18).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to have modified the system of Song with the aforementioned features from Prasad with the motivation of developing a system having the ability to process requests for reconfiguring different data repositories as recited in Prasad (Col. 2, Ln. 8-14).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to have used the software system of Song in a biomedical development process with the motivation of developing a system with a greater capability of meeting FDA audit requirements.

(B) As per claim 2, in the combined system of Song in view of Prasad the biomedical development phases include phases selected from the group consisting of discovery phase, clinical studies phase, Food and Drug Administration (FDA) approval phase, product release phase, and combinations thereof (Song: Col. 2, Ln. 10-23).

(C) As per claims 3-8, 20-21 and 34, the combined system of Song in view of Prasad teaches metadata data structures but does not expressly teach the specific data recited in claims3-8, 20-21 and 34; however, these differences are only found in the non-functional descriptive material and are not functionally involved in the steps recited nor do they alter the recited structural elements. The recited method steps would be performed the same regardless of the specific data. Further, the structural elements remain the same regardless of the specific data. Thus, this descriptive material will not distinguish the claimed invention from the prior art in terms of patentability, *see In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); In re Lowry, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994); MPEP 2106.*

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have included these data types recited in the above mentioned claims with the motivation of providing a more comprehensive data analysis system to be used in the biomedical development phase.

(D) As per claim 9, the combined system of Song in view of Prasad teaches a second metadata data structure contained within the database that describes the data collected during a second biomedical development phase, said second biomedical development phase occurring approximately after the first biomedical development phase (Prasad: Col. 3, Ln. 8-17 and Col. 4, Ln. 29-35). The motivation for modifying Song with these aforementioned features from Prasad is the same as that was set forth in the rejection of Claim 1.

(E) As per claim 10, the combined system of Song in view of Prasad comprises:

at least one second graphical user interface connected to the database that collects data during the second biomedical development phase (Song: Col. 5, Ln. 27-31), wherein structure of the second graphical user interface is defined based at least in part upon the second metadata data structure so that the second graphical user interface collects data points as well as second metadata that is to be stored within the second metadata data structure, said second metadata describing the collected data points (Prasad: Col. 3, Ln. 8-17 and Col. 4, Ln. 29-35),

wherein at least a portion of the second metadata is determined based upon an issue which arises in a biomedical development phase that occurs approximately subsequently to the second biomedical phase (Prasad: Col. 2, Ln. 1-18). The motivation for modifying Song with these aforementioned features from Prasad is the same as that was set forth in the rejection of Claim 1.

(F) As per claim 11, in the combined system of Song in view of Prasad the second biomedical development phase is a clinical studies phase (Song: Col. 10-23)(Note: Product development phases in the biomedical industry involve clinical studies), wherein the second metadata data structure includes data that specifies interrelationships between tests conducted during the second biomedical development phase (Prasad: 8-18). The motivation for modifying Song with these aforementioned feature from Prasad is the same as that set was forth in the rejection of Claim 1.

(G) As per claims 12-15, in the combined system of Song in view of Prasad data links exist between the first metadata stored in the first metadata data structure and the second metadata stored in the second metadata data structure in order to form an audit trail (Prasad: Col. 3, Ln. 8-18 and Song: Col. 19-23). (Note: Relational databases, as disclosed by Prasad, provide data links between various metadata sets).

In Song the audit trial is used during an FDA approval phase to determine a biomedical product development trail associated with the first and second biomedical development phases (Song: Col. 2, Ln. 10-23). (Note: The FDA audits the records dealing with various product development processes in part to approve the products).

The examiner takes the position that the first metadata is used during an FDA approval phase to determine how tests were conducted during the first biomedical development phase, wherein the second metadata is used during the FDA approval phase to determine how tests were conducted during the second biomedical development phase. (Note: The purpose of the FDA audit is the examine the methodology of the tests).

(H) As per claims 16-18, in the combined system of Song in view of Prasad the examiner takes the position that the first biomedical development phase in Song is the discovery phase and the second development phase is the clinical studies phase (the discovery phase is commonly the first phase in a development process and the clinical studies phase is commonly the second phase in a development process), wherein at least a portion of the first metadata data structure is determined based upon an issue that arises in the FDA approval phase. (Song: Col. 2, Ln. 10-23). Song does not teach that the issue that arises in the FDA approval process that defines at least a portion of the first metadata data structure is an FDA requirement that patients be tested who are taking a predetermined medication. The examiner takes the position that it is well known in the biomedical and pharmaceutical industry that patients who are taking a predetermined medication be tested and at the time of the invention it would have been obvious for one of ordinary to have added this criteria to the development process in order to prevent patients who are taking a predetermined medication from having adverse reactions and in order to isolate or at least identify those patients which may be an aberrational affect on the data obtained from the biomedical development phase.

(I) As per claim 19, the examiner takes Official Notice that it is well known in the art to select the third party from another company division, a different company, the FDA or combinations thereof. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have selected these particular individuals with the motivation of having a pool of participants who are readily available to participate in the study.

(J) As per claims 22-29, these claims repeat features previously addressed in the rejection of claims 1-21 and are rejected on the same basis.

(K) As per claim 30, in the combined system of Song in view of Prasad the identifier is a uniform resource locator (URL) that identifies data and metadata as associated with the first biomedical project and owned by the first company (Prasad: Claim 16). The motivation for making this modification to the system of Song is the same as that was set forth in the rejection of Claim 1.

(L) As per claims 31-33, the examiner takes Official Notice that it is well known in the art to limit or allow the access rights of another entity to certain portions of the data and that access to portions of this data is protected by user names and passwords. At the time of the invention, it would have been obvious for one of ordinary skill in the art to have added these features in the combined system of Song in view of Prasad with the motivation of preventing unauthorized users from gaining access to the data and also for preventing an entity participating in the biomedical development phase from gaining access to data after its role in the biomedical phase had been completed.

(M) As per claims 35, this claim repeats features previously addressed in the rejection of claims 1-33 and are rejected on the same basis.

(N) As per claim 36, the combined system of Song in view of Prasad further comprises:

a second metadata data structure contained within the database that describes the data collected during a second biomedical development phase, said second biomedical development phase occurring approximately after the first biomedical development phase (Prasad: Col. 4, Ln. 29-35);

a third metadata data structure contained within the database that describes the data collected during a third biomedical development phase, said third biomedical development phase

occurring approximately after the second biomedical development phase (Prasad: Col. 4, Ln. 29-35);

a fourth metadata data structure contained within the database that describes the data collected during a fourth biomedical development phase, said fourth biomedical development phase occurring approximately after the third biomedical development phase (Prasad: Col. 4, Ln. 29-35),

wherein the data links associate genomic data with data contained within at least the second metadata data structure (Prasad: Col. 3, Ln. 13-18).

The motivation for modifying Song with these aforementioned features from Prasad is the same as that was set forth in the rejection of Claim 1.

wherein FDA approval is sought for a biomedical product directed to people with first genetic characteristics, said first genetic characteristics being identified based upon analysis of the genomic data that is associated with the data in the second metadata data structure (Song: Col. 2, Ln. 10-23). (Note: Song does not specifically recite that the products which are being developed are products for which FDA approval is sought for a biomedical product directed to people with first genetic characteristics, the first genetic characteristics being identified based upon analysis of the genomic data that is associated with the data in the second metadata structure. However, the examiner takes the position that it is well known in the biomedical industry to develop products for people with certain genetic characteristics (e.g. people who carry a gene for a certain disease) and at the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the combined system of Song in view of Prasad with this limitation with the motivation of providing products to people who carry a given

gene for a disease so that the chances that these people will develop this disease will be reduced if they used newly developed biomedical product.

Conclusion

6. Any inquire concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. The fax telephone number for this group is (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

Vivek Koppikar

2/23/2006

C. LUKE GILLIGAN
PATENT EXAMINER